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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/005,956	12/03/2001	Zenta Tsuchihashi	D0053 NP	9972

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EXAMINER	
JOHANNSEN, DIANA B	

ART UNIT	PAPER NUMBER
1634	

DATE MAILED: 03/25/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	10/005,956	TSUCHIHASHI ET AL.	
	Examiner	Art Unit	
	Diana B. Johannsen	1634	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *1* MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *18 July 2002* .

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-50* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-50* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

ELECTION/RESTRICTION

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-17, drawn to isolated nucleic acids, classified in at least, for example, class 536, subclass 23.5.

II. Claims 22-23 and 25-27, drawn to methods of "constructing haplotypes," classified in at least, for example, class 435, subclass 6.

III. Claims 18-21, 24-27, and 48-50, drawn to methods of analyzing and genotyping nucleic acids, classified in at least, for example, class 435, subclass 91.5.

IV. Claims 28-31 and 43-47, drawn to methods of diagnosing risk of developing a disorder, classified in at least, for example, class 435, subclass 91.2.

V. Claims 32-36, drawn to nucleic acid libraries, classified in at least, for example, class 435, digest 22.

VI. Claims 37-42, drawn to kits comprising primers, classified in at least, for example, class 536, subclass 24.33.

It is noted that claims 25-27 depend in the alternative from claims 21 and 23. Accordingly, claims 25-27 have been included both in Group II and Group III, and if either of these Groups is elected, will be examined only to the extent that they are drawn to the elected invention.

2. The inventions are distinct, each from the other because of the following reasons:

Inventions I, V, and VI are patentably distinct products. While each of the Inventions are composed of nucleotides, Inventions I, V, and VI have different structural and functional properties. Specifically, the products of Invention I are individual molecules "derived from" particular human genes and including "at least one "polymorphic position;" such molecules function in, e.g., protein synthesis. The products of Invention V are libraries, or combinations, of multiple nucleic acid molecules; such combinations function in, e.g., methods of simultaneous screening for multiple polymorphisms. The products of Invention VI are oligonucleotides that function in, e.g., nucleic acid sequencing. Accordingly, Inventions I, V, and VI have different structural and functional characteristics, and are patentably distinct from one another.

Inventions I and II, I and III, and I and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the isolated nucleic acids of Invention I may be used in a materially different process, such as methods of cloning and protein synthesis.

Inventions V and II, V and III, and V and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the

libraries of Invention V may be used in a materially different process, such as methods of screening for gene homologues or methods of chromosomal mapping.

Inventions VI and II, VI and III, and VI and IV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case, the primers of Invention VI may be used in a materially different process, such as methods of labeling nucleic acids.

Inventions II, III, and IV are patentably distinct methods having different objectives and requiring the performance of different process steps. Invention II requires a step of "grouping" nucleic acids to achieve the objective of "constructing haplotypes." Invention III requires a step of determining nucleic acid sequence to achieve the objective of "analyzing" a nucleic acid sample. Invention IV requires a step of amplifying nucleic acids with primers to achieve the objective of identifying risk of a disorder. Accordingly, Inventions II, III, and IV are patentably distinct from one another.

Election Requirements Applicable to Groups I-VI

3. Groups I-VI are drawn to multiple patentably distinct molecules/polymorphisms and/or multiple patentably distinct combinations of molecules/polymorphisms, and to methods requiring detection or use of multiple patentably distinct molecules/polymorphisms and/or multiple patentably distinct combinations of molecules/polymorphisms. Specifically:

Group I encompasses numerous molecules derived from one of several patentably distinct genes (genes having different structures and different functions), which molecules comprise "at least one" polymorphic position. The various molecules encompassed by the claims each have a different structure and different functional properties, and a reference against one molecule would not be a reference against another. Accordingly, the numerous molecules encompassed by Group I are patentably distinct from one another.

Group II is drawn to methods of constructing haplotypes employing at least two of the molecules of Group I. Accordingly, Group II encompasses the use of any combination of two or more of the numerous polymorphic molecules of Group I. The various individual molecules of Group I are patentably distinct from one another, as discussed above. Further, each combination of molecules has a different structure and is characterized by a different combination of functional properties. Accordingly, each combination of molecules is patentably distinct from each other combination.

Groups III-IV are drawn to methods having different objectives and employing different steps to accomplish detection of one or more of the numerous polymorphisms and polymorphic molecules of Group I, which polymorphisms and polymorphic molecules, and combinations thereof, are patentably distinct from another, as discussed above.

Group V is drawn to libraries comprising one or more "polymorphic positions" of the genes set forth in the claims. Thus, Group V comprises numerous nucleic acid libraries, each with a different structure and each characterized by a different

combination of functional properties. Accordingly, the numerous libraries of Group V are patentably distinct from one another.

Group VI is drawn to kits comprising sequencing primers, which primers hybridize to "at least one" polymorphic position of one of the genes recited in the claims. Each primer and each combination of primers has a different structure, and functions in sequencing or amplification of a different polymorphic site or combination of sites. Accordingly, each such primer or combination is patentably distinct from every other primer or combination.

Accordingly, in view of the above:

If Group I is elected, Applicant is further required to elect one isolated nucleic acid comprising a polymorphic position or positions for examination;

If Group II is elected, Applicant is further required to elect one combination of "at least two" nucleic acids for use in constructing haplotypes;

If Group III or IV is elected, Applicant is further required to elect one polymorphic position or one combination of polymorphic positions;

If Group V is elected, Applicant is further required to elect one library of nucleic acids; and

If Group VI is elected, Applicant is further required to elect one primer or one combination of primers.

This is not an election of species. Applicant is advised that examination will be restricted to only the elected invention (i.e., the elected molecule(s) or polymorphism(s)).

Further, Applicant must identify the SEQ ID NO or combination of SEQ ID Nos corresponding to the elected Invention (if applicable), as well as the claims readable on the elected invention.

4. Because Inventions I-VI are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification and recognized divergent subject matter, and because Inventions I-VI, as well as the numerous structurally and functionally distinct molecules/polymorphisms and combinations thereof encompassed by Groups I-VI, require different sequence and text searches that are not co-extensive, examination of these distinct inventions would pose a serious burden on the examiner, and therefore restriction for examination purposes as indicated is proper.

5. Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

6. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

7. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diana B. Johannsen whose telephone number is

703/305-0761. The examiner can normally be reached on Monday-Friday, 7:30 am-4:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached at 703/308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are 703/872-9306 for regular communications and 703/872-9307 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703/308-0196.

Diana B. Johannsen
March 23, 2003